

Conclusion: Our institution experience with oral tacrolimus for GVHD prophylaxis supports continuation of this practice as a viable alternative to IV tacrolimus and results in significant cost savings.

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Palifermin Use in Lymphoma Patients Undergoing Autologous BEAM Transplants

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Background: Palifermin is a human recombinant keratinocyte growth factor. It was approved by the FDA in 2004 for decreasing the incidence and duration of oral mucositis in patients receiving high dose chemotherapy and stem cell rescue. Approval followed two randomized, placebo-controlled, multicenter trials conducted in patients with hematologic malignancies undergoing myeloablative conditioning with TBI. After approval, palifermin use was extended to non-TBI based conditioning regimens. In 2008, our institution began use of palifermin in lymphoma patients undergoing BEAM conditioning and ASCT. Our goal in this study was to assess the efficacy of such a strategy in a non-TBI based transplant group.

Methods: From 1/2008 through 6/2013 we performed 75 BEAM/ASCT on lymphoma patients using palifermin. We compared this group to the preceding 75 lymphoma patients who received BEAM auto-conditioning without it. The two cohorts were compared for incidence of fever, positive blood cultures, positive urine cultures, TPN use, PCA use, and length of stay (LOS). Data was collected retrospectively.

Results: Results are summarized in the table below. Of note, there was a statistically significant difference ($p < 0.05$) of fewer febrile episodes in the palifermin group and TPN use. However there were no statistically significant differences in positive blood cultures, urine cultures, PCA use, or LOS.

Conclusion: Mucositis has been associated with increased incidence of fever. Inflammation rather than infection has been postulated as the mechanism for mucositis fever. Significantly fewer patients developed fevers in the palifermin group though there was no difference in the incidence of positive cultures. Palifermin reduced the use of fever workups and the empiric use of antibiotics. TPN use was also curtailed by palifermin administration. Despite its mechanism of action of decreasing mucositis, neither PCA use nor LOS differed substantially between the groups. It may be that mucositis is not a major rate-limiting step to discharge as symptoms often tend to resolve shortly after engraftment. Further analysis comparing time to engraftment with length of stay may help

Table

Comparison of Patient Arms (Palifermin vs. No Palifermin)

Characteristic	Palifermin (N=75)	No Palifermin (N=75)	P-value
Fever	46	72	<0.05
Positive Blood Cultures	5	11	NS
Positive Urine Cultures	11	5	NS
TPN	17	58	<0.05
PCA	52	56	NS
Mean LOS	21	22	NS
Median LOS	21	21	NS
Range for LOS	12-36	12-37	N/A

NS: Not statistically significant (using P value of < 0.05)

answer this question. Important future studies should include pharmacoeconomic analysis of the relationship between palifermin, TPN antibiotics, and growth factor use as well as overall cost and outcomes of performing BEAM/ASCT with and without palifermin. A CIBMTR retrospective study with additional data collection analyzing palifermin use in BEAM autopatients may be an expeditious way to answer many of these questions.

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A Prospective, Randomized Clinical Trial of Cryotherapy Vs. Supersaturated Calcium Phosphate Rinses Vs. Saline Rinses for the Prevention of Oral Mucositis in Patients with Multiple Myeloma (MM) Receiving High-Dose Melphalan (HDM) and Autotransplantation

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Background: Oral mucositis (OM) is a major complication of HDM. Previous studies analyzing the role of oral cryotherapy (CT) in the prevention of OM are small or include patients treated with multiple conditioning regimens.

Study Purpose: To compare the efficacy of CT plus saline solution (SS) mouth rinse vs. SS alone vs. supersaturated calcium phosphate rinses (Caphsol®) to prevent HDM-induced OM in patients with MM undergoing autotransplantation

Methods: One hundred and seventeen MM patients, scheduled to receive HDM (140-200 mg/m²) followed by autotransplantation at the Audie L. Murphy Memorial Veterans Hospital in San Antonio, Texas, were randomized to the above mentioned groups (Table 1). Patients were assessed daily for OM until discharge or resolution of OM, using the World Health Organization (WHO) mucositis scale. Duration

Table 1

Patient Characteristics

	Total	Caphsol®	Cryotherapy	Saline Solution	p-value
Patients, n	117	39	40	38	
Age, median (range)	62 (39-75)	62 (45-68)	62 (39-75)	61.5 (43-70)	0.7696
Gender, n (%)					0.8962
Male	110 (94)	36 (92)	38 (95)	36 (95)	
Female	7 (6)	3 (8)	2 (5)	2 (5)	
Race/Ethnicity, n (%)					0.5164
Caucasian	56 (48)	23 (59)	16 (40)	17 (45)	
African Americans	40 (34)	11 (28)	15 (37)	14 (37)	
Hispanic	21 (18)	5 (13)	9 (23)	7 (18)	
Karnofsky score, n (%)					0.8394
70	1 (1)	0 (0)	1 (2.5)	0 (0)	
80	16 (14)	6 (15)	6 (15)	4 (11)	
90	100 (85)	33 (85)	33 (82.5)	7 (89)	
Serum Creatinine, mean (SD)	1.12 (0.67)	1.28 (0.93)	1.00 (0.29)	1.09 (0.63)	0.1715
Diabetes, n (%)					0.9912
Yes	30 (26)	10 (26)	10 (25)	10 (26)	
No	87 (74)	29 (74)	30 (75)	28 (74)	
Dentures, n (%)					0.6336
Yes	32 (27)	9 (23)	13 (32)	10 (26)	
No	85 (73)	30 (77)	27 (68)	28 (74)	
Smoking, n (%)					0.9122
Yes or history	89 (76)	30 (77)	30 (75)	29 (76)	
Never	28 (24)	9 (23)	10 (25)	9 (24)	